

**510(k) Summary for
INNOVANCE™ D-Dimer Assay**

OCT 24 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K081732

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer: Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring Str. 76
D-35001, Marburg Germany

Contact Information: Siemens Healthcare Diagnostics Glasgow Site
P.O. Box 6101 Newark, Delaware 19714
Attn: Kathleen Dray-Lyons Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: September 3, 2008

2. Device Name/ Classification: INNOVANCE™ D-Dimer
INNOVANCE™ D-Dimer Controls

Class: Fibrinogen and Fibrin Split Product, Antigen, Antiserum and controls, Class II
21 CFR 864.7320
Panel: Hematology (HE)
Product Code: DAP

3. Identification of the Legally Marketed Device:

Stratus® CS DDMR TestPak, CalPak, DilPak- k063356
Advanced D-Dimer Controls 1 and 2 – k992956

4. Device Description:

Polystyrene particles covalently coated with a monoclonal antibody (8D3) are aggregated when mixed with samples containing D-dimer. The D-dimer cross-linkage region has a stereosymmetrical structure, i.e. the epitope for the monoclonal antibody occurs twice. Consequently, one antibody suffices in order to trigger an aggregation reaction, which is then detected turbidimetrically via the increase in turbidity.

5. Device Intended Use:

INNOVANCE™ D-Dimer:

For the quantitative determination of cross-linked fibrin degradation products (D-dimers) in human plasma on the Siemens and Sysmex Coagulation Systems. The INNOVANCE™ D-Dimer assay is intended for use as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)].

INNOVANCE™ D-Dimer Controls:

INNOVANCE™ D-Dimer Control 1 and INNOVANCE™ D-Dimer Control 2 are assayed, normal and pathological level, intralaboratory quality controls for assessment of precision and analytical bias in the quantitative determination of D-dimer on the Siemens and Sysmex Coagulation Systems.

6. Medical device to which equivalence is claimed and comparison information:

The INNOVANCE™ D-Dimer and INNOVANCE™ D-Dimer Controls are substantially equivalent to the Stratus® CS DDMR TestPak, CalPak, DilPak (k063356) and Advanced D-Dimer Controls 1 and 2 (k992956). The INNOVANCE™ D-Dimer method, like the Stratus® D-Dimer method, is intended for the quantitative determination of cross-linked fibrin degradation products containing D-dimer in human plasma and aids in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)].

7. Device Performance Characteristics:

Method Comparison

Regression Statistics

Comparative Method	Slope	Intercept mg/L FEU	Correlation Coefficient	n
Stratus® CS DDMR	0.951	0.059	0.97	318

In the correlation studies, D-dimer values ranged between 0.18 and 4.39 mg/L FEU.

Clinical Study Summary

Instrument	VTE Patients	Cutoff (mg/L FEU)	Sensitivity (%)	Specificity (%)	NPV (%)	Frequency of VTE (%)
BCS® Systems	902	0.5	97	42	98	22.0



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 24 2008

Siemens Healthcare Diagnostics
Ms. Kathleen Dray-Lyons
500 GBC Drive M/S 514
Newark, Delaware 19702

Re: k081732

Trade/Device Name: Innovance D-Dimer and Innovance D-Dimer Controls
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/Fibrin Degradation Products Assay
Regulatory Class: Class II
Product Code: DAP
Dated: October 16, 2008
Received: October 17, 2008

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

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predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Maria Chan, Ph.D
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081732

Device Name: **INNOVANCE™ D-Dimer**

INNOVANCE™ D-Dimer Controls

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Prescription Use X AND/OR Over-The-Counter-Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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